IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application of:
U.S. Patent No. 5,750,338

Mark L. Collins *et al.*

Reissue Serial No. 09/533,906

Reissue Application Filed: March 8, 2000

For: TARGET AND BACKGROUND CAPTURE METHODS WITH AMPLIFICATION FOR AFFINITY ASSAYS

Group Art Unit: 1634

Examiner: *[unassigned]*

INFORMATION DISCLOSURE STATEMENT ACCOMPANYING PROTEST UNDER 37 CFR § 1.291(a)

ATTENTION: REISSUE LITIGATION BOX 7
Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

The following information is brought to the attention of the Examiner. The items listed on the attached form PTO-1449, submitted pursuant to 37 C.F.R. 1.291(b)(1), are relied on in the protest filed herewith. Copies are enclosed for the convenience of the Examiner.

The following is a concise explanation of the relevance of each of the listed items.

CERTIFICATE OF DELIVERY

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being hand delivered to Group Art Unit 1634 on the date shown below, addressed to the Commissioner for Patents, Reissue Litigation Box 7, Washington, D.C. 20231

Thinh Nguyen
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8/2/00
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Signature of Person Delivering Paper

U.S. Patent No. 4,554,088 (Whitehead *et al.*) discloses the use of single-stranded nucleic acid bound to dispersible magnetic beads to isolate complementary nucleic acid from a sample in a ligand-ligate binding reaction (*e.g.*, see column 17, lines 15-57).

U.S. Patent No. 4,563,419 (Ranki *et al.*) discloses a hybridization assay in which a target nucleic acid is (1) separated from other sample components by hybridizing the target to a complementary nucleic acid fragment affixed onto a nitrocellulose filter and (2) detected with a labeled probe.

U.S. Patent No. 4,672,040 (Josephson) discloses isolation of specific DNA or RNA fragments from a mixture of nucleic acid fragments, including the desired species, by using immobilization of a known probe to magnetic particles and placing the coupled particles in contact with the mixture to allow hybridization, followed by magnetic separation of the particles from unbound materials, and washing of the hybridized fragments on the magnetic particles (*e.g.*, see column 17, line 48 to column 19, line 10).

U.S. Patent No. 4,683,202 (Mullis) discloses the polymerase chain reaction (PCR) method of nucleic acid amplification.

EPO Publication No. 0 328 829 is the published (Aug. 23, 1989) European patent application that corresponds to U.S. application no. 07/136,920, that is substantially identical to the disclosure of the present reissue application.

Arsenyan *et al.*, *Gene* 11:97-108 (1980) discloses the isolation and amplification of rat liver 5S RNA genes that relies on preliminary enrichment of the genes, followed by amplification by bacterial cloning. For preliminary enrichment of the 5S RNA genes, the individual (+) and (-) gene strands are captured from a sample containing denatured DNA fragments on solid supports with bound capture probes (oligo(dT) cellulose or 5S cDNA-cellulose). The (+) and (-) strands are separated from the sample, eluted from the solid supports, hybridized together, cloned into a vector, and amplified in *E. coli* transformants grown *in vitro*.

Blumenthal, *Proc. Natl. Acad. Sci. U.SA.* 77(5):2601-2605 (1980) discloses transcription of RNA species mediated by the enzyme Qß replicase under particular conditions.

Boss et al., ***J. Biol. Chem.,*** **256(24):12958-12961 (1981)** discloses isolation of a target yeast iso-1-cytochrome c (CYC1) mRNA by hybridization to a complementary cloned DNA attached to a solid matrix (*e.g.*, diazobenzyloxymethyl cellulose powder), followed by sequencing using a CYC1-specific oligonucleotide primer and the dideoxy chain termination method. The sequencing reaction produces a multitude of sequences from the target nucleic acid, which are detected by gel separation and autoradiography.

Brown ***et al., Ann. Rev. Biochem.*** **43:667-693 (1974)** discloses methods of isolating nucleic acid sequences by using polynucleotides fixed to insoluble matrices, and the desirability of combining nucleic acid isolation with subsequent amplification. Brown et al., at pages 673-674, discloses DNA purification by using an affinity column in which complementary RNA or DNA molecules are fixed to an insoluble support (*e.g.*, nitrocellulose or cellulose) and circulating the soluble DNA mixture through the affinity column. Brown et al., at page 687, paragraph 2, states that "purification of important structural genes will have to be coupled with some method in which a small amount of a given gene can be increased enormously in amount. After purification has enriched the gene sequence … the remaining DNA would be amplified hundreds to thousandsfold in amount…. The amplification step might be carried out in vitro by an efficient DNA polymerase, which would replicate faithfully each molecule of DNA many times."

Burgess, "Purification and Physical Properties of ***E. coli*** **RNA Polymerase"** ***in*** **<u>RNA Polymerase</u> (Losick and Chamberlin, eds.) (Cold Spring Harbor Laboratory, Cold Spring Harbor, NY, 1976), part 1: 69-100**, discloses procedures for purifying RNA polymerases and determining enzyme purity, commonly associated enzymatic contaminants (pages 86-89) and properties of RNA polymerases.

Feinberg ***et al., Anal. Biochem.*** **132:6-13 (1983)** discloses a radiolabeling method that uses random hexamer oligonucleotide primers to initiate non-specific enzymatic reproduction of isolated polynucleotides.

Gaubatz ***et al., Biochim. Biophys. Acta,*** **825:175-187 (1985)** discloses a method of cDNA strand displacement synthesis to amplify mRNA sequences.

Kornberg, DNA Synthesis (W.H. Freeman & Co., San Francisco, CA, 1974), page 65 ("Substrates"), discloses the effects of enzymatic contaminants on DNA polymerase mediated reactions, such as an endonuclease that may "convert an active template-primer into an inhibitor that binds the enzyme in an unproductive complex", an exonuclease that "can enlarge nicks into gaps" or "an excess of nuclease [that] would lead to net loss of DNA."

Maniatis et al., Molecular Cloning, A Laboratory Manual (Cold Spring Harbor Laboratory, Cold Spring Harbor, NY 1982), Chapter 6, pages 187-196, discloses methods of isolating RNA that include inhibiting RNases or inactivating nucleases, and selecting poly(A)+ RNA using oligo(dT)-cellulose. It emphasizes the need to use nuclease-free laboratory ware and to carefully prepare solutions to avoid contamination.

Maniatis et al., Molecular Cloning, A Laboratory Manual (Cold Spring Harbor Laboratory, Cold Spring Harbor, NY 1982), Chapter 7, pages 213-214, discloses synthesis of first strand cDNA using reverse transcriptase, emphasizing problems associated with contaminating RNase in the reaction.

McGraw-Hill's *Biotechnology Newswatch* 6(19): 8 (Oct. 6, 1986), "DNA cleavage adapter groomed for genetic diagnostics" at paragraph 7, quotes K. Mullis, inventor of the polymerase chain reaction (PCR), stating that his technique results in "a lot of other things replicating that you don't want." The article describes a combination of PCR with other techniques to produce an improved diagnostic assay.

Orkin, *N. Engl. J. Med.,* 317(16):1023-1025 (1987) discloses the use of elevated temperature and heat-stable polymerase in PCR to minimize the problem of background amplification due to cross-hybridization of primers to non-target sequences at a lower temperature (see page 1024, column 2).

Polsky-Cynkin *et al., Clin. Chem.,* 31(9):1438-1443(1985) discloses sandwich hybridization assays in which a target DNA is captured by a complementary probe affixed to a solid support (beads, polypropylene test tubes or polypropylene solid-phase receptacles), and detected on the solid support by using a radiolabeled probe.

Powell ***et al., Cell,*** **50:831-840 (1987)** discloses capture of poly(A)$^+$ RNA from a sample by using oligo(dT)-cellulose chromatography, followed by PCR amplification of cDNA made from the eluted RNA and detection of the amplified products by using radioactively labeled oligonucleotides (see Experimental Procedures on pages 838-839).

Saiki ***et al., Nature*****, 324: 163-166 (1986)**, discloses that reduced signals in a assay based on PCR amplification may result from failure to purify target DNA, *i.e.*, "inhibition of the amplification process by cellular debris" (see text spanning page 164, column 2 to page 165, column 1).

Syvänen ***et al., Nuc. Acids Res.*****, 14(12):5037-5048 (1986)** discloses a hybridization assay in which a target nucleic acid is captured by hybridization to a capture probe with an affinity label (*e.g.*, biotin) and then binds to an affinity matrix (e.g., streptavidin agarose beads) through an affinity interaction (*e.g.*, biotin-avidin interaction). The capture probe and target nucleic acid are hybridized in solution to take advantage of solution-phase kinetics (see pages 5042-5043).

Thompson ***et al., Clin. Chem.,*** **35(9): 1878-1881 (1989)** discloses a hybridization assay that combines reversible target capture, essentially as disclosed in the present reissue application, with enzymatic amplification (PCR) of the purified target nucleic acid.

This information has been served on applicant in accordance with 37 C.F.R. 1.248, as indicated by the attached proof of service.

Respectfully submitted,

Date: August 1, 2000

By: ______________________

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